Summary of Safety and Effectiveness
Liquichek Urine Toxicology Control (Screen Series)

1.0 Submitter

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Date of Summary Preparation

December 16, 2003

2.0 Device Identification

Product Trade Name: Liquichek Urine Toxicology Control (Screen Series)

- ☐ Liquichek Urine Toxicology S1 Control
- ☐ Liquichek Urine Toxicology S2 Control
- ☐ Liquichek Urine Toxicology S3 Control
- ☐ Liquichek Urine Toxicology S1 Low Opiate Control
- ☐ Liquichek Urine Toxicology S2 Low Opiate Control
- ☐ Liquichek Urine Toxicology S1E Control
- ☐ Liquichek Urine Toxicology S2E Control
- ☐ Liquichek Urine Toxicology S1E Low Opiate Control
- ☐ Liquichek Urine Toxicology S2E Low Opiate Control

Common Name:	Drug Mixture Control
Classifications:	Class I
Product Code:	DIF
Regulation Number:	21 CFR 862.3280

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Urine Toxicology Control

Bio-Rad Laboratories
Irvine, California

Docket Number: K021411

4.0 Description of Device

Liquichek Urine Toxicology Controls are prepared from human urine with added drugs of abuse and metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquichek Urine Toxicology Controls are intended for use as quality controls urine to monitor the performance of laboratory urine toxicology screening* procedures.
*[S1E/S2E: enzyme immunoassay (EIA)]

6.0 Comparison of the new device with the Predicate Device

The new Liquichek Urine Toxicology Controls claim substantial equivalence to the Liquichek Urine Toxicology Controls currently in commercial distribution (K021411).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	**Bio-Rad Liquichek Urine Toxicology Control** (Screen Series) (New Device)	**Bio-Rad Liquichek Urine Toxicology Control** (Screen Series) (Predicate Device K021411)
Similarities		
Intended Use	Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology screening procedures.	Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology screening procedures.
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage (Unopened)	2-8°C until expiration date	2-8°C until expiration date
Open Vial	30 days at 2-8°C	30 days at 2-8°C
Drugs	Same as the predicate device	11-Nor-Δ-9-THC-9-COOH, Amphetamines, d-Amphetamine, Barbiturates, Benzodiazepines, Benzoylecgonine, Cannabinoids, Cocaine, Ethanol, Lysergic Acid Diethylamide (LSD), Methadone, Methaqualone, Morphine (Free), Nordiazepam, Nortriptyline, Opiates, Phencyclidine, Propoxyphene, Secobarbital, Tricyclic Antidepressants
Differences		
Levels	S1, S2, S3, S1E, S2E, S1 Low Opiate and S2 Low Opiate. Includes new levels added to the product line: S1E Low Opiate and S2E Low Opiate	S1, S2, S3, S1E, S2E, S1 Low Opiate and S2 Low Opiate. Does not include levels: S1E Low Opiate and S2E Low Opiate
Preservatives & Label Warnings	Antibiotic Preservative cocktail Does not require hazard symbols	Contains 0.1% Sodium Azide Requires hazard symbols

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Urine Toxicology Control (Screen Series). Product claims are as follows:

7.1 Open vial: All analytes are stable for 30 days when stored tightly capped at 2-8°C.

7.2 Shelf Life:

- S1E, S2E, S1E Low Opiate, S2E Low Opiate: Two years stored at 2-8 °C
- S1, S2, S3, S1 Low Opiate, S2 Low Opiate: Three years stored at 2-8 °C

7.3 Real time studies will be ongoing to support the shelf life of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 3 2004

Ms. Elizabeth Platt
Regulatory Affairs Manager/Quality Assurance
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k033924
Trade/Device Name: Liquichek Urine Toxicology Control
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I
Product Code: DIF
Dated: December 16, 2003
Received: December 18, 2003

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K033924

Device Name:

Liquichek Urine Toxicology Control

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- ☐ Liquichek Urine Toxicology S2E Control
- ☐ Liquichek Urine Toxicology S1E Low Opiate Control
- ☐ Liquichek Urine Toxicology S2E Low Opiate Control

Indications for Use:

Levels S1, S2, S3, S1 Low Opiate, and S2 Low Opiate

Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology screening procedures.

Levels S1E, S2E, S1E Low Opiate and S2E Low Opiate

Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033924

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X or Over-the Counter use_____